

REMARKS

In view of the substance of the interview of November 30, 2004, the Applicants herein respectfully request non-entry of their most-recent Amendment filed October 29, 2004. The Applicant herewith presents amendments to claim 1 to clarify the language highlighted by the Examiner.

Claims 1, 4-7, 9-10, 12-14, and 45 are pending. The Applicants kindly thank the Examiner for the interview and herein respectfully requests further examination of the application and reconsideration of the claims, in view of the amendments and remarks presented herewith.

The Applicant herewith presents amendments to fully address the issues raised by the Examiner. Claim 1 now particularly points out and defines a novel method in view of the references cited for directly monitoring volatile compounds in a gas or vapor phase medium from a nucleic acid polymerase chain reaction, in real-time during the reaction. The Applicant respectfully requests the Examiner to withdraw all rejections.

The Examiner is respectfully referred to page 26, line 12 to page 27, line 18 of the instant Specification. The Applicant indeed respectfully highlight the necessary distinction of the limitation of the amended claims presented herewith, i.e., a method of directly monitoring volatile compounds in a gas or vapor phase medium in real-time during the polymerase chain reaction. The Applicants have clarified the subject matter of the instant claims as requested by the Examiner by particularly pointing out the proper steps of the method of the invention.¹

¹ The Applicants have removed the previously recited step of attaching one or more volatile organic tags to the nucleic acid(s), per the interview discussion of November 30, 2004. This step, with which the Examiner has expressed confusion as to proper order in the method of the invention, is an optional preliminary step of the method of the present invention; and, accordingly, is an unnecessary limitation to distinguish the cited art.

REJECTIONS UNDER 35 USC §102**A. Van Ness '893 "Methods and compositions for determining the sequence of nucleic acid molecules"**

The Van Ness '893 disclosure provides a method for sequencing nucleic acids that fundamentally and necessarily requires, in the order, 1) separation of nucleic acid fragments according to size, 2) cleavage of a tag from the nucleic acid, and 3) detection of the tag. The Examiner's position is articulated that Van Ness discloses enzymatic cleavage and that the Applicant's previously claimed method has been indistinguishable. The Applicant respectfully amends the scope of the claims now pending to fully address this issue. Indeed, since all subject matter of the instant claims now pending is limited to a method for *directly* monitoring volatile compounds in a gas or vapor phase medium from a nucleic acid *polymerase chain reaction*, *during* the reaction, none of the claims encompass anything within the disclosure of Van Ness.

The Applicant therefore respectfully request the Examiner to withdraw the rejection under 35 USC §102 in view of Van Ness '893.

B. Koster ('394) "Automated Process Line"

The Applicant respectfully remind the Examiner that anticipation, *per se*, under 35 USC §102 necessarily requires that all of the limitations of a pending claim must be disclosed in a single prior art reference. To anticipate a claim, the reference must teach every element of the claim. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Koster, et al., is directed toward an automated process line for evaluating the results of a large amount of completed reactions pertaining to a large amount of different samples, i.e., "continuously processing reaction vessels one after another ... the APL [automated process line] can run unattended continuously with a continuous sample throughput and is capable of analyzing on the order of 10,000-50,000 genotypes per day." Koster, ¶10-11. The Examiner is particularly referred to Koster ¶65:

In steps where sample vessels are to be sealed, such as when subjected to PCR amplification, or unsealed, such as for reagent addition or removal, an automated lid application/removal and sealing system may be integrated into the system. Examples of these include a lid parking station, such as is available from Robocon, and a plate sealer,

such as the "MJ Microseal", available from MJ Research. A system turntable might also be employed to assist the system robot in orienting the samples for delivery into each station of the APL. Such a turntable is available, for example, from Robocon. Additionally, a shaker is also included in the APL system in embodiments where beads or other reagents are added to the sample for immobilizing the sample, or where other manipulations requiring mechanical shaking are involved. [Emphasis added]

The Examiner is also particularly referred to Koster ¶96:

After PCR amplification, the plates are removed from the PCR reaction station 162 by the robot 150. The plates are then moved to the lid park station 158, where the lids are removed and unsealed. As noted above, however, a penetrable seal such as a foil wrap or parafilm is an alternative to a lid seal, and if removable lids are not used to seal the plates, then the lid park station is unnecessary and the next substance that must be added to the wells of the plate will be inserted upon piercing of the foil wrap. [Emphasis added]

Koster, however, does not teach or contemplate a method for directly monitoring volatile compounds in a gas or vapor phase medium from a polymerase chain reaction, during the reaction. Koster merely contemplates a system in abstract terms that can evaluate a solid-phase reaction by means of mass spectrometry, preferably *after the reaction is completed*. DNA sequencing using mass spectrometry. See, e.g., Koster paragraphs 82, 83, 96.

It is improper, in determining whether a person of ordinary skill would have been led to a solution to a problem, simply to "[use] that which the inventor taught against its teacher." W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Koster paragraphs 108-125, as cited by the Examiner, merely contemplates a system in abstract terms that can evaluate a solid-phase reaction by means of mass spectrometry. Koster, however, does not contemplate any embodiments that fall within the Applicant's claims now presented.

The Applicant, accordingly, respectfully requests the Examiner to withdraw the rejection.

Rejections under 35 USC §103

The subject matter of claims 4-6 and 45 is rejected as obvious in view of the disclosure of Van Ness ('893) combined with Freidhoff ('115) and Van Ness ('893) combined with Koster ('394), respectively.

The Applicant respectfully point out the necessary distinction of the polymerase chain reaction limitation of the amended claims presented herewith, i.e. directly monitoring volatile compounds in a gas or vapor phase medium during the reaction. The '893 disclosure provides a method for sequencing nucleic acids that fundamentally and necessarily requires, in the order, 1) separation of nucleic acid fragments according to size, 2) cleavage of a tag from the nucleic acid, and 3) detection of the tag. The method of the present invention, in sharp contrast, is drawn toward a method for directly monitoring volatile compounds in a gas or vapor phase medium from a polymerase chain reaction, during the reaction. This language patentably distinguishes now presented claims 4-6 and 45 to the instant invention.

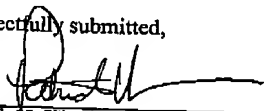
The Applicant respectfully requests the Examiner to withdraw the rejections.

For all the foregoing reasons, the Applicant submits that Claims 1, 4-7, 9-10, 12-14, and 45 are in condition for allowance. Early action toward this end is courteously solicited.

The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1943.

The Examiner is kindly encouraged to telephone the undersigned in order to expedite any detail of the prosecution.

Respectfully submitted,


Patrick H. Higgins
Reg. No. 39,709
Attorney for Applicants
(609) 896-7654

DATE: November 30, 2004

FOX ROTHSCHILD LLP, 997 Lenox Drive, Building 3, Lawrenceville, NJ 08648-2311